

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of adding human chorionic gonadotropin to frozen thawed embryo transfer cycles in women with history of thin endometrium: A clinical trial

Protocol summary

Summary

Objective: We design this study in order to assess adding human chorionic gonadotropin (HCG) to the conventional protocol in endometrial preparation in women with thin endometrium and a history of in vitro fertilization-embryo transfer (IVF-ET) failure. Design: 28 infertile women with thin endometrium are studied in this non-randomized clinical trial study (quasi experimental design) from September 2013 to January 2014. Inclusion and Exclusion criteria: Infertile women who are candidate for frozen-thawed (ET) with at least 2 previous failed IVF cycle, thin endometrium (thickness less than 7 mm) despite conventional treatment in previous IVF cycles (vaginal estrogen, sildenafil, vitamin E, ...). Patients with intrauterine lesion such as sub mucosal leiomyoma, history of endometriosis, and thyroid disorders are excluded. Intervention: All the patients receive 8 mg estradiol valerate from the second day of menstrual cycle and continued at least for seven days. HCG (Pregnyl®, Darou Pakhsh, Iran) are administered (150 IU, IM) from the 8th day of cycle. On the 12-13th day Trans-vaginal sonography are done and endometrial thickness are measured. If it are proper, (at least 7mm) HCG stop and after 24 h progesterone 100 mg intramuscular are injected for 3 days. Finally, ET are performed. Main outcome measures: The pregnancy test (serum β HCG) was done two weeks after ET. Fetal heartbeat (clinical pregnancy) was checked after 2-3 weeks after positive β HCG test .

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201512082604N2**

Registration date: **2016-01-14, 1394/10/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-14, 1394/10/24

Registrant information

Name

Robab Davar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 7085

Email address

davar@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Expected recruitment start date

2013-09-01, 1392/06/10

Expected recruitment end date

2015-01-01, 1393/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding human chorionic gonadotropin to frozen thawed embryo transfer cycles in women with history of thin endometrium: A clinical trial

Public title

Effect of adding human chorionic gonadotropin to frozen thawed embryo transfer cycles with history of thin

endometrium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women who are candidate for frozen-thawed (ET); with at least 2 previous failed IVF cycle, thin endometrium (thickness less than 7 mm) despite conventional treatment in previous IVF cycles (vaginal estrogen; sildenafil; vitamin E; ...). Exclusion criteria: Oocyte donation; Endometriosis; Polycystic Ovary Syndrome; Intrauterine lesion such as submucosal leiomyoma; history of endometriosis; and thyroid disorders.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Research and Clinical Center for Infertility, Shahid Sadoughi University of Med

Street address

Research and Clinical Center for Infertility, Bouali Ave, Safaeyeh, Yazd, Iran.

City

Yazd

Postal code

8916877391

Approval date

2014-06-23, 1393/04/02

Ethics committee reference number

317

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

2-3 weeks after positive pregnancy test

Method of measurement

Fetal heartbeat after 2-3 weeks.

2

Description

Chemical pregnancy

Timepoint

2 weeks after embryo transfer

Method of measurement

serum β HCG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All the patients receive 8 mg estradiol valerate from the second day of menstrual cycle and continued at least for seven days. HCG (Pregnyl®, Darou Paksh, Iran) are administered (150 IU, IM) from the 8th day of cycle. On the 12-13th day Trans-vaginal sonography are done and endometrial thickness are measured. If it are proper, (at least 7mm) HCG stop and after 24 h progesterone 100 mg intramuscular are injected for 3 days. Finally, ET are performed

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility

Full name of responsible person

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Research and Clinical Center for Infertility, Bouali Ave., Safaeyeh, Yazd, Iran.

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Full name of responsible person

Dr. Robab Davar

Street address

Research and Clinical Center for Infertility, Bouali Ave, Safaeyeh, Yazd, Iran.

City

yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences, Bouali Av

Full name of responsible person

Dr. Robab Davar

Position

Gynecologist/Infertility Fellowship (M.D.)/ Associated Professor of Shahid Sadoughi University of me

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty